

### **REMARKS**

Claims 1-7, 9-11 and 21-32 are pending in this application. Claim 7 has been cancelled without prejudice. Claims 1 and 21 have been amended. Claims 37 and 38 have been added. No new matter has been added. Thus, claims 1-6, 9-11, 21-32, 37 and 38 will be pending after entry of this Amendment. Reconsideration of the claims is respectfully requested.

#### **Information Disclosure Statement (IDS)**

The Applicants are submitting herewith a 3<sup>rd</sup> IDS. The Examiner is respectfully requested to review the references and make them of record.

#### **35 U.S.C. § § 102 / 103 Claim Rejections**

##### **Independent Claim 1**

Claim 1 recites a working electrode, a counter electrode, a mediator, “the oxidizable species being different than the mediator species and having different redox potentials” and “said mixture being located as a single layer on at least a portion of the working electrode and the counter electrode prior to the introduction of the test sample.” The present invention is advantageous because “[s]ince the internal reference concentration is fixed, the calibration scope of the sensor will only depend on the sensor response for glucose while the intercept will depend on the added amount of the internal reference. In [ ]other words, the internal reference will only offset the intercept and will not change the calibration scope.” Page 4, lines 9-13 of the patent application.

The applied reference of U.S. Patent No. 6,033,866 to Guo (“Guo”) does not disclose, teach or suggest “said mixture being located as a single layer on at least one of the working electrode and the counter electrode prior to the introduction of the test sample” as recited in claim 1.

Rather, Guo discloses a glucose biosensor 10 that is based on a two mediator – two enzyme redox system. Col. 2, lines 3-5. Guo discloses a face-to-face configuration of its electrodes in which the first redox mediator is contained in the conductive layer of the sensing electrode and the second redox mediator is contained in the reagent strip located between the

electrodes. Col. 2, lines 10-16. In addition to the second redox mediator system, the reagent strip of Guo further includes two enzymes – glucose oxidase and horseradish peroxidase. Col. 2, lines 31-34.

As shown in FIG. 1D of Guo, the biosensor 10 has multiple layers including sensing electrode 20, reagent strip 16, whole blood separating membrane 38 and reference electrode 30. There is no disclosure, let alone a teaching or suggestion that the claimed mixture can be located as a single layer with a portion located on the working and counter electrodes. The biosensor 10 of Guo is more complex using its multiple layers, multiple reagents and multiple mediators and does not offer the simplicity of the claimed test sensor especially in its manufacturability. In fact, Guo appears to teach away from less complicated test sensors (e.g., sensors using a single mediator) by the following passage:

Although amperometric sensors using a single mediator can be used to assay glucose, none really provides the combination of a wide response range, rapid response, a high degree of accuracy and precision over a wide response range and high sensitivity so that even relatively low concentrations of glucose such as found in urine could be assayed.

Therefore, claim 1 is not anticipated by or rendered obvious over Guo. Thus, claim 1 should be in a condition for allowance.

#### Dependent Claims 2-6, 9-11 and 37

To address further deficiencies in Guo, the Office Action has applied additional references (U.S. Patent No. 5,520,786 to Bloczynski (“Bloczynski”) and U.S. Publication No. 2004/0245121 to Nagakawa (“Nagakawa”) to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Guo. Thus, dependent claims 2-6, 9-11 and 37 are not anticipated by or rendered obvious over Guo, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 1.

Therefore, claims 2-6, 9-11 and 37 should be in a condition for allowance.

#### Independent Claim 21

Claim 21 recites a method of forming and placing a reagent mixture and includes, *inter alia*, “forming a batch of reagent mixture by adding an enzyme, adding a mediator and adding an oxidizable species, the added oxidizable species being added separately from the mediator”

and “after forming the reagent mixture, placing the reagent mixture at least partially on the working electrode and the counter electrode of the biosensor prior to the introduction of the fluid sample.” Guo does not teach, disclose or suggest forming such a mixture prior to the introduction of the fluid sample. Rather, before the fluid sample is introduced, Guo discloses a first redox mediator being contained in the conductive layer of the sensing electrode and a reagent system including a second redox mediator system and two enzymes glucose oxidase and horseradish peroxidase. See col. 2, lines 10-16 and 31-34.

U.S. Publication No. 2001/0052470 to Hodges (“Hodges”) also does not disclose, teach or suggest the feature of claim 21. Rather, Hodges discloses using a mediator (ferricyanide) that reacts and forms a product ferrocyanide. Paragraph 9 of Hodges. Hodges discloses that after the reaction is complete, the concentration of ferrocyanide indicates the initial concentration of glucose. *Id.* This is done after the introduction of a fluid sample. Furthermore, Hodges does not disclose, teach or suggest adding the oxidizable species separately from the mediator prior to the introduction of the sample. Therefore, claim 21 is not anticipated by or rendered obvious over Guo or Hodges. Thus, claim 21 should be in a condition for allowance.

#### Dependent Claims 22-32 and 38

To address further deficiencies in Guo or Hodges, the Office Action has applied additional references (Bloczynski and Nagakawa) to selected claims. However, neither Bloczynski nor Nagakawa addresses the above noted deficiencies in Guo and Hodges. Thus, dependent claims 22-32 and 38 are not anticipated by or rendered obvious over Guo, Hodges, Bloczynski, Nagakawa or any combination thereof for at least the reasons discussed above in claim 21.

Therefore, claims 22-32 and 38 should be in a condition for allowance.

#### Conclusion

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. The Commissioner, however, is authorized to deduct the cost of the RCE of \$810.00, the two month extension fee of \$490.00 and any other fees (except the

payment of the issue fee) from Nixon Peabody Deposit Account No. 50-4181, Order No. 247082-000168USPX.

Respectfully submitted,

Date: November 5, 2010

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